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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/544,632	04/06/2000	Goro Hori	506.35379CC2	9269

20457 7590 05/07/2003

ANTONELLI TERRY STOUT AND KRAUS  
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ARLINGTON, VA 22209

EXAMINER
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KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 05/07/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/544,632**

Applicant(s)  
**Hori**

Examiner  
**Gollamudi Kishore**

Art Unit  
**1615**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 3, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 17, 18, and 28-48 is/are pending in the application.
- 4a) Of the above, claim(s) 17 and 28-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18 and 35-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

Art Unit: :1615

### **DETAILED ACTION**

**The filing under 1.114 dated 2-3-03 is acknowledged.**

**Claims included in the prosecution are 18 and 35-48. Claims 17 and 28-34 remain withdrawn.**

#### **Claim Rejections - 35 USC § 112**

**1. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

**2. Claims 29-30, 36-37, 45 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

**These claims recite treating with phospholipase. It is unclear as to what phospholipase applicant is referring to. There are different phospholipases, A and D for example and the function of one of the phospholipases is to remove the phosphate head group and when this is removed, the lipid is no longer a phospholipid. The specification does not adequately define this term.**

Art Unit: :1615

*Claim Rejections - 35 U.S.C. § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 18 and 35-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugano (J. Nutr., 1990) or Sugano (Atherosclerosis, 1988) by themselves or in combination with Imaizumi (Agri. Biol. Chem., 53, (9), 1989 of record.

As pointed out above, these references teach the effectiveness of soybean protein-phospholipid complexes in lowering the cholesterol levels (note the abstracts and Tables in both). The amounts of phospholipids in Sugano however, are lower than the amounts in instant invention.

Imaizumi teaches that the administration of phospholipids causes the reduction in the serum cholesterol levels (note the abstract).

It would have been obvious to alter the amounts of the phospholipids in the phospholipid-soy protein complex in Sugano, with the expectation of obtaining the best possible results, since Imaizumi teaches that phospholipids by themselves lower the cholesterol. The criticality of the enzyme modified phospholipid is not readily apparent to

Art Unit: :1615

the examiner; as pointed out above, the specification does not provide a definition or experiments conducted with this product.

5. Claims 18 and 35-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugano (J. Nutr., 1990) or Sugano (Atherosclerosis, 1988) by themselves or in combination with Imaizumi (Agri. Biol. Chem., 53, (9), 1989 of record as set forth above, further in view of Jenkins (Nutrition Reports International, 1983) also of record.

Jenkins while disclosing the effects of dietary protein and lecithin on plasma lipids, lipoproteins and cholesterol, teaches that the level of dietary lecithin controls the effect of the source and type of protein on the lipid metabolism (note the abstract).

Therefore, it would have been obvious to vary the amounts of lecithin in the compositions of Sugano, 1990 and 1988 since as pointed out above, Imaizumi teaches that phospholipids by themselves lower the cholesterol and Jenkins teaches that the level of dietary lecithin controls the effect of the source and type of protein on the lipid metabolism.

6. Claims 18 and 35-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirtori (Ann. Nutr. Metab. 1985) in combination with Williams (Perspectives in Biology and Medicine, 1984).

Sirtori teaches the effectiveness of lecithinated soy proteins in lowering cholesterol (note the abstract). The amount of lecithin in the complex however, is lower than the amount in instant invention.

Art Unit: :1615

**Williams teaches the effectiveness of phospholipids in cholesterol removal (note the entire article).**

**It would have been obvious to alter the amounts of the phospholipids in the lecithinated soy proteins in Sirtori with the expectation of obtaining the best possible results since Williams teaches that phospholipids by themselves lower the cholesterol.**

**Therefore, it would have been obvious to vary the amounts of lecithin in the compositions of Sugano, 1990 and 1988 since as pointed out above, Williams teaches that phospholipids by themselves lower the cholesterol and Jenkins teaches that the level of dietary lecithin controls the effect of the source and type of protein on the lipid metabolism.**

**7. Claims 18 and 35-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirtori (Ann. Nutr. Metab. 1985) in combination with Williams (Perspectives in Biology and Medicine, 1984), Jenkins (Nutrition Reports International, 1983).**

**Sirtori teaches the effectiveness of lecithinated soy proteins in lowering cholesterol (note the abstract). The amount of lecithin in the complex however, is lower than the amount in instant invention.**

**Williams teaches the effectiveness of phospholipids in cholesterol removal (note the entire article).**

**Jenkins as pointed out above, while disclosing the effects of dietary protein and lecithin on plasma lipids, lipoproteins and cholesterol, teaches that the level of dietary**

Art Unit: :1615

lecithin controls the effect of the source and type of protein on the lipid metabolism (note the abstract).

Therefore, it would have been obvious to vary the amounts of lecithin in the compositions of Sirtori since Williams teaches that phospholipids by themselves lower the cholesterol and Jenkins teaches that the level of dietary lecithin controls the effect of the source and type of protein on the lipid metabolism.

Applicant's arguments based on the declaration have been fully considered, but are not found to be persuasive. Applicant, based on the declaration, argues that the combination produces a synergistic effect. These arguments are not found to be persuasive for the following reasons. First of all, in experiment I applicant only compares the amounts of lecithin in the complex. There are no corresponding experiments with the same amounts of phospholipid alone to come to the conclusion that the results are synergistic. The data presented in Table II of the declaration appears to show an additive effect with regard to both serum cholesterol and the liver cholesterol; as evident from the prior art, soybean protein and lecithin each by itself has the ability to lower cholesterol and therefore, an additive effect is to be expected and it is not an unexpected finding. Secondly, these studies were performed with only soybean protein and not with hydrolysates or wheat protein; claims recite these besides soybean protein. The studies are also not commensurate with the scope of the claims in terms of 'enzyme modified phospholipids or lecithin.

Art Unit: :1615

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.



Application/Control Number: 09/544,632

Page 8

Art Unit: :1615

**Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.**



**Gollamudi S. Kishore, Ph. D**

**Primary Examiner**

**Group 1600**

*gsk*

**May 5, 2003**